

Job Description

Job title Innovation Lead – Manufacturing, Equipment Validation and Regulatory Readiness

Faculty/Directorate: HLS

Grade: F/34 (Externally funded – UKRI)

Role profile: Research Assistant R1

Leadership and Management Level: N/A

Part time (50% FTE)

Fixed term (31.07.27)

	Duties of the role
Overall purpose of the role	Provides expert leadership for the establishment and operation of the prototype manufacturing capability, with accountability for coordinating technical delivery, process control, validation evidence and regulatory readiness within defined delegated authority. The postholder will work closely with Chromar's research and commercial teams, external technical and regulatory partners, and project personnel to translate laboratory formulations into reproducible prototype formats, including powders, gels and other delivery formats. The role will also provide technical leadership and supervision for project students and other personnel undertaking formulation, materials processing, characterisation and prototype development.
Main duties and responsibilities	- Leads installation, commissioning and technical acceptance of Chromar manufacturing and processing equipment, including electrospinning, powder processing, filling and associated equipment. - Reporting line: Formally line managed by Chromar's CEO, the post holder will also report to Chromar's CSO. Outside of weekly meetings with CEO and CSO, independent decision-making powers are delegated in line with operational efficiencies; formulation adjustments or strategies would require approval; facilitative decisions around working with those formulations are delegated to the postholder. - Postholder will develop, recommend and implement equipment qualification, commissioning and validation protocols, including installation, operational and performance qualification where appropriate. Formal and final approvals will be made by CEO and CSO. - Postholder will make recommendations on and prepare/maintain equipment documentation, operating procedures, calibration records, maintenance schedules and technical validation reports. Will report to CEO and CSO for final approval/sign off.

Duties of the role

- To develop and maintain standard operating procedures (SOPs), work instructions, manufacturing protocols and batch documentation for Chromar processes. To establish reproducible processes for the preparation, processing and manufacture of Chromar biomaterial formulations and prototype products. Support scale-up from laboratory formulations to prototype manufacturing while maintaining appropriate process controls, traceability and documentation. Postholder will be subject to acceptance criteria set by CEO and CSO in all aspects specified above.
- Conduct and document laboratory, equipment and process risk assessments, including identification of hazards, control measures and safe operating requirements according to university policies.
- Lead process development and optimisation, including investigation of formulation, processing and equipment parameters that influence product quality and performance. Develop appropriate in-process and final-product checks to assess consistency, quality and suitability of manufactured prototypes. Postholder will postholder analyse process variability, determine appropriate controls, evaluate results and recommend or implements technically justified changes at the agreement of CEO and CSO. Coordinate day-to-day technical activities associated with prototype production, equipment uses, materials preparation and experimental programmes.
- Maintain accurate technical records relating to equipment, materials, manufacturing processes, deviations and process development activities. Postholder will have the delegated authority to stop manufacturing, reject or quarantine materials, suspend equipment use, require corrective action or prevent activity that does not meet safety, quality or process requirements.
- Provide technical supervision and technical direction to project students and junior personnel undertaking experimental and manufacturing activities. Ensure that students and personnel working within the facility are appropriately trained in equipment operation, SOPs, risk controls and laboratory/manufacturing practices.
- At the direction of CEO and CSO, work with external regulatory, quality and technical partners to support Chromar's regulatory strategy and MHRA-related activities. Contribute technical evidence and documentation to MHRA registration activities and other regulatory requirements relevant to Chromar's intended product classification and route to market. Postholder will prepare documentation only, CEO and CSO own the regulatory strategy, product classification, submissions, communications with the MHRA and final sign-off.
- Liaise with regulatory consultants and external partners to respond to technical information requests, identify documentation gaps and coordinate actions required for regulatory readiness. Postholder will provide information and coordinate responses, negotiate technical requirements, if necessary, but formal representation will be made by CEO and CSO.
- Coordinate the preparation, review and organisation of technical documentation required to support regulatory submissions and product registration, ensuring that information generated through formulation,

	Duties of the role
	manufacturing, testing and validation activities is appropriately documented and traceable. • Support preparation and maintenance of technical files, product specifications, manufacturing documentation, risk assessments, validation records and other regulatory documentation required for the progression of Chromar prototypes towards market registration. Ensure that formulation, manufacturing and testing records generated within Chromar are suitable for incorporation into regulatory and quality documentation. Postholder takes ownership of day-to-day management of the laboratory or manufacturing facility, equipment inventory, maintenance arrangements, risk controls and user competencies. • Work with Chromar's academic and commercial partners to support technology development, prototype manufacture, testing and preparation for subsequent regulatory and translational activities. • Contribute technical information to grant applications, technical reports, intellectual property development and commercialisation activities at the direction of CEO and CSO. • Identify equipment, process and manufacturing requirements for future development and scale-up of the Chromar platform. • Postholder will recommend, not control budgets/expenditures for equipment, consumables, maintenance, calibration and external technical or regulatory services. • Physical and environmental demands: The role will involve an anticipated 25% FTE laboratory time (half of the postholder's time), involving some standing for prolonged periods but this is not compulsory and rest breaks are easily integrated into laboratory workflows of the post. The role involves hazard exposure from mechanical equipment usage in formulation production, also from general manufacturing processes, where the implementation and maintenance of correct PPE and exclusion zones are the direct responsibility of the Postholder. Manual handling is envisaged in equipment installation and operation, and good lifting and handling practice training will be undertaken by the Postholder upon appointment as part of general university induction processes. Act in accordance with DMU Values: • Collaborative – Work together to achieve joint outcomes, understand how your work contributes to DMU, and be aware of your personal impact on others. • Compassionate – Be open, honest, and caring, work on a basis of trust, and hold yourself accountable for your actions. • Creative - Strive for better, challenge bureaucracy, explore digital solutions, and innovate creatively. • Community minded - Embrace alternative views, treat others with respect, and tackle inequalities. • Treat all DMU staff, students, contractors and visitors with dignity and

	Duties of the role
	respect. Provide a service that complies with the Equality Act 2010, eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations with particular attention to the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief (or none), sex and sexual orientation. All members of staff are responsible for their contribution to improved environmental performance and in reducing greenhouse gas emissions at DMU. It is therefore required that all members of staff are aware of how the Environmental Policy relates to their own role at the University. Staff conduct must reflect the values inherent in the Environmental Policy and where required staff must cooperate with environmental compliance and conformance requirements to help minimise our emissions to air, water and land. The postholder should have a positive attitude towards health and safety, and be aware of and comply with all health and safety policies for the university, as applicable. There will be a requirement to complete all mandatory health and safety training as deemed to be relevant for the position held. The postholder is expected to help maintain a safe working environment for staff, students and visitors by working closely with the local safety coordinator as required. Any accidents or dangerous incidents must be reported promptly through the university's reporting system.

Person Specification

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Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
Qualifications & Training	Degree or equivalent experience in pharmaceutical science, pharmaceuticals, chemical engineering, materials science, biomedical engineering or a related discipline.	Essential		✓			✓
	Experience of developing and following controlled experimental or manufacturing procedures at commercial batch production level. Degree of experience: minimum of 1 year post-graduate.	Essential		✓	✓		✓
Previous Work Experience	Experience of equipment installation, commissioning, qualification, validation or technical troubleshooting.	Essential		✓	✓		✓
	Experience of preparing SOPs, risk assessments, protocols and technical documentation.	Essential		✓	✓	✓	✓
	Experience of working with regulatory or quality documentation, including MHRA-related activities.	Essential		✓	✓		✓

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
	Experience of supervising or providing technical guidance to students, researchers or laboratory personnel.	Essential		✓	✓		✓
	Experience of developing and following controlled experimental or manufacturing procedures.	Essential		✓	✓		✓
Specific Knowledge/Skills /Abilities	Ability to develop reproducible manufacturing and processing procedures and investigate process variability.	Essential		✓	✓		✓
	Experience with powder processing, milling, filling or other particulate/materials processing technologies.	Desirable		✓	✓	✓	✓
	Knowledge of quality-by-design, process development, equipment qualification or technology-readiness progression.	Desirable		✓	✓		✓
	Experience of working with external regulatory consultants or technical partners.	Desirable		✓	✓		✓
	Experience of prototype development and translational research.	Desirable		✓	✓		✓
Organisation	Strong organisational, documentation and problem-solving skills.	Essential		✓	✓		✓

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
Communication/ presentation skills	An experienced communicator of scientific findings to mixed audiences, capable of delivering updates, results, findings and problems in a timely and concise manner at regular intervals as required.	Essential		✓	✓	✓	✓
Motivation and attitude	Ability to work independently while coordinating effectively with multidisciplinary research, commercial and external partner teams.	Essential		✓	✓		✓
Other requirements	Excellent record keeping, time keeping and communication skills.	Essential		✓	✓		✓
	Living close to Leicester or ability to commute easily to campus to perform lab-based tasks when required.	Desirable		✓	✓		✓
Our Values and Behaviours at DMU							
Collaborative	Support colleagues to achieve outcomes whilst being aware of personal impact of individual contribution and impact on colleagues	Essential		✓	✓		
Compassionate	Act openly and honestly, showing care to others and holding oneself accountable for own actions	Essential		✓	✓		
Creative	Striving for better, offering constructive challenge to creatively explore solutions and innovations to improve	Essential		✓	✓		
Community-minded	Treating others with respect, demonstrating empathy and embracing alternative views and values whilst seeking to tackle inequalities	Essential		✓	✓		
Our Values and Behaviours at DMU (if manager/leader)							
Collaborative	Foster team collaboration and the exchange of best practices, establish clear and ambitious goals, develop work plans focused on achieving outcomes, and identify and nurture individual strengths to support development	Essential		✓	✓		
Compassionate	Offer honest and constructive feedback, cultivate a secure and open workplace, make difficult decisions with credibility, and act with integrity and transparency	Essential		✓	✓		
Creative	Cultivate an environment that promotes questioning and idea sharing, minimises	Essential		✓	✓		

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
	bureaucratic hurdles, encourages open dialogue about mistakes, and engages the teams in ongoing service improvement.						
Community-minded	Encourage diverse viewpoints, swiftly address conflicts and inappropriate behaviours, and nurture a culture of mutual respect.	Essential		✓	✓		

*A = Application Form; I = Interview; T = Test; D = Documentary Evidence